UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION OPIATE LITIGATION	))	MDL No. 2804
	))	Case No. 17-md-2804
This document applies to All Cases.	)))	Judge Dan Aaron Polster

SECOND ORDER AMENDING PROTECTIVE ORDER
RE DEA ARCOS/DADS DATABASE

By Order of this Court filed March 6, 2018, at Docket #167, the Court entered an initial

Protective Order re the DEA ARCOS/DADS Database.[1] On May 8, 2018, at Docket #400, the

Court entered an Amendment to Protective Order to make such Order expressly applicable to

Suspicious Order Reports (SORs) produced by DOJ and/or DEA. These two Orders are

collectively referred to as the "ARCOS Protective Order." With the agreement of the Department

of Justice ("DOJ"), Drug Enforcement Administration ("DEA") and the Co-Lead Counsel for the

Plaintiffs in MDL No. 2804 ("MDL Counsel"), the Court hereby amends the ARCOS Protective

Order in the following respects:

1)   The Court concludes that disclosure may be made to counsel for the governmental

plaintiffs, which include cities, counties, and Native American Tribes and hospitals in this

litigation and for litigation existing in any court throughout the United States involving the

marketing, distribution, sale or use of Opioid related drugs and/or for law enforcement purposes

("Opioid Litigation") of any or all of the following: (1) the entirety of the SORs previously

produced in this litigation by the DEA; (2) the entirety of the unprocessed ARCOS data previously

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[1] All references to "Docket #" refer to the master docket in *In re: National Prescription Opiate Litig.*, Case No. 1:17-MD-2804 (DAP) (N.D. Ohio).

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produced in this litigation by the DEA; (3) county level SLCG[2] Processed ARCOS data; and/or (4) county level reports[3] including the following:

a. County Level Distributor Reports that include the following information:

   i. State level summary distributor market share by MME;

   ii. State level summary distributor market share by dosage units;

   iii. State level summary distributor market share by dosage units by distributor family;

   iv. State versus county level market share comparison by total dosage units;

   v. County level summary distributor market share by MME;

   vi. County level summary distributor market share by dosage units;

   vii. County level distributor summary chart;

   viii. County level summary distributor market share by dosage units by distributor family;

   ix. County level per capita total dosage units;

   x. Chart of county level market share and total dosage units per capita;

   xi. County level market share by distributor;

   xii. Charts of county level market share by distributor.

b. County Level Labeler Reports that include the following information:

   i. County level labeler[4] market share by MME total for 2006 through 2014;

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[2] Securities Litigation and Consulting Group, Inc

[3] The county level reports include data for all drugs for which the DEA provided ARCOS data except the two treatment drugs, specifically, methadone and buprenorphine.

[4] Labeler information was derived using the National Drug Code Number assigned to the product under the National Drug Code System of the Food and Drug Administration code for each drug and cross referencing against the Food and Drug Administration, National Drug Code Directory and list of NDC/NHRIC Labeler Codes. A list of NDC/NHRIC Labeler Codes is available at:
https://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm191017.htm. Food and Drug Administration, National Drug Code Directory available at:
https://www.deadiversion.usdoj.gov/arcos/ndc/ndcfile.txt; https://www.deadiversion.usdoj.gov/arcos/ndc/readme.txt. Additionally, the ARCOS Registrant Handbook provides the following definitions relating to labeler: A packer/repacker is a registrant that packs a product into a container (i.e., packer) or repacks a product into different size containers, such as changing a package of 50 capsules to 5 packages of 10 capsules each. A labeler/relabeler is a

    ii. County level labeler market share by dosage units total for 2006 through 2014;

    iii. County level labeler market share by MME by year;

    iv. County level labeler market share by dosage units by year;

    v. County level labeler market share data by MME;

    vi. County level market share data by dosage units.

    c.   County Level Pharmacy Reports that include the following information:

    i. County level listing of all opioid shipments to all pharmacies within the county by total dosage units, weight in mgs and total MME;

    ii. County level summary of all opioid shipments to all pharmacies within the county;

    iii. County level listing by distributor by year of total dosage units, mgs and MME as well as average pharmacy MME in county, average pharmacy MME in the state and MME percale in state;

    iv. For each pharmacy in the county reports showing:

        1. opioid shipments by distributor by year;

        2. chart of total dosage units by drug family shipped to pharmacy;

        3. chart of total MME by drug family shipped to pharmacy;

2)   The Court also concludes that disclosure may be made to counsel for the hospitals who are plaintiffs in the MDL solely for use in this litigation. Disclosure may not be made to counsel for any hospitals who are not plaintiffs in the MDL for any other purpose.

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registrant that affixes the original label to a product (i.e., labeler) or changes in any way the labeling on a product without affecting the product or its container (i.e, relabeler). The "relabel" term implies that the package size remains unchanged with changes being made only in brand name, NDC number, distributor, etc. Registrant Handbook at 6-2, available at:
https://www.deadiversion.usdoj.gov/arcos/handbook/full.pdf#search=arcos%20handbook.

2)3)   The MDL Counsel are hereby authorized to transfer the data requested by counsel

in Opioid Litigation under paragraph 1) to a secure computer file or site and subsequently

provide access to attorneys representing cities, counties, or Native American Tribes or

hospitals in Opioid Litigation filed in federal, state, or tribal courts within the United States,

for litigation or law enforcement purposes. The MDL Counsel are further authorized to

transfer the data requested by counsel for the hospital plaintiffs in the MDL under

paragraph 2) to the same secure computer file or site and subsequently provide access to

attorneys representing the hospital plaintiffs in the MDL solely for use in this litigation.

3)4)   Such secured site shall be set up pursuant to Attachment A to this Order.

4)5)   All lawyers and parties must read the ARCOS Protective Order, as amended by this

Order, and sign the Acknowledgement of Protective Order and Agreement to be bound,

which is attached as Attachment B to this Order.

5)6)   All other provisions of the ARCOS Protective Order shall remain in full force and

effect as if repeated verbatim herein.

IT IS SO ORDERED.

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Dan Aaron Polster
United States District Judge

ATTACHMENT A

Transfer Process and Procedure

The MDL shall store the data made available to counsel in Opioid Litigation pursuant to the ARCOS Protective Order on a highly secure online website hosted on Amazon Web Services, "AWS", secured servers.
Access to the website and then ability to un-encrypt the data is secured by two separate passwords. The website home page shall have an initial User ID and password dialog box.

    a. When valid User ID and password is entered, the county or counties that registered user is entitled to see data for is shaded dark green with the rest of the USA map light grey, or a non-graphic option may be used that allows the user to see.

    b. There will be a terms and conditions including recognition of the protective order and agreement to security of the data sign-off at this point before the registered user can download any data on each visit.

    c. Once the "I Accept" or similar button is struck, Securities Litigation and Consulting Group, Inc. (SLCG) will be notified that the registered user has signed on and has access to a data file.

The integrity of the data will be protected by SLCG and by the authorized users who have committed to the protective order as a pre-condition to downloading any data.